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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,014	12/04/2001	Chen Xing Su	10209.276	6898

21999 7590 10/09/2007

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EXAMINER	
OH, SIMON J	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/006,014	SU ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and request for continued examination, all received on 14 September 2007.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 September 2007 has been entered.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is hereby withdrawn in view of the present amendment to the claims.

Claims 1, 3-10, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to methods of treating pain where a dose of *Morinda citrifolia* juice is present in an amount of about 2.31% by volume. Claim 1 further stipulates that this dose is to be given twice per day. Claim 9 further stipulates that each dose of juice is in an amount between 2 and 3 ounces. There is no support in the instant specification for such claim limitations. The instant specification contains only a disclosure on Page 15 where in a biochemical assay, a concentration of 2.31 percent yielded COX-1 inhibition of 20% and COX-2 inhibition of almost 60%. There is no further statement as to whether this percentage is intended to mean the *Morinda citrifolia* juice itself or only a component of the juice.

Furthermore, the instant claims recite that the juice is present in an amount of about 2.31% by volume. The disclosure only indicates a concentration of 2.31%, not "about 2.31 percent".

Furthermore, the instant specification does not indicate that the concentration is expressed as a volumetric percentage, rather than another expression of concentration, such as mass percentage.

Furthermore, although the instant specification discloses positive results of the assay at a concentration of 2.31%, there is not a sufficient disclosure to show that this then leads to the twice-daily administration of *Morinda citrifolia* juice at a concentration of 2.31% by volume, as recited in Claim 1.

Furthermore, although the instant specification discloses positive results of the assay at a concentration of 2.31%, there is not a sufficient disclosure to show that this then leads to the

administration of a dose of *Morinda citrifolia* juice where 2.31% of the total volume of the dose to be administered is part of a total dose of about 2 to 3 ounces.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 9, 10, 12, and 13 under 35 U.S.C. 103(a) as being unpatentable over Gidlund is maintained.

Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gidlund (U.S. Patent No. 6,436,449).

The Gidlund patent teaches the use for an extract derived from the fruits, leaves, bark or roots of *Morinda citrifolia*. Fruit extracts may be either liquid, as pressed from the fruits and processed in the ways conventional to the art; or they may be processed into a powder (See Abstract; and Column 4, Lines 19-30). The liquid extract of *Morinda citrifolia* will be present in an amount ranging from 0.1 mL to 2 mL per kilogram of body weight of the patient. The dry extract of *Morinda citrifolia* will be present in an amount ranging from 5 mg to 200 mg per kilogram of body weight of the patient (See Column 5, Lines 16-23). Specific dosages will depend on factors such as age and general state of health (See Column 5, Lines 42-49). The medicament containing the *Morinda citrifolia* may be in various forms, including a liquid solution, emulsion, or suspension, granules, pills, capsules, and tablets, to be administered in a single daily dose or several daily doses (See Column 5, Lines 56-62).

Although the Gidlund patent is directed towards methods of treating tinnitus, it is disclosed that in other prior art, that *Morinda citrifolia* is known to be useful for other conditions, such as menstrual cramps, arthritis, gastric ulcers, sprains, injuries, and pain (See Column 2, Lines 3-19). It is the position of the examiner that one of ordinary skill in the art would be able to treat a patient for these conditions using the general guidelines disclosed in the Gidlund patent with a reasonable expectation of success. It is also the position of the examiner that the dosage ranges disclosed within the Gidlund patent read on the dosage ranges claimed in the instant application. Therefore, it is the position of the examiner that the property of selective COX-2 inhibition is inherent in the compositions disclosed in Gidlund. Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

The applicant's arguments, received on 14 September 2007, have been considered, but are not found to be persuasive.

The applicant's present amendment necessitates a rejection based on new matter. The previous rejection based on new matter has been withdrawn and the present rejection on new matter is detailed above.

As stated in previous Office Actions, the examiner considers the property of selective cyclooxygenase-2 inhibition to be implicit and inherent to the disclosure of the prior art. As the art has already shown guidance that the invention of the Gidlund reference is useful for treating various conditions of pain, such as menstrual cramps, arthritis, sprains, and injuries, the examiner considers such a disclosure to be further guidance and evidence towards that rationale.

Furthermore, it is well within the level of skill of one of ordinary skill in the art to adjust dosages in order to not only optimize medicinal effectiveness, but also to mitigate unpleasant side effects. The basis for the applicant's case for patentability lies squarely within this realm.

The applicant is reminded that a composition known in the prior art does not become patentable upon the discovery of a new property. See MPEP § 2112. The burden remains on the applicant to show the unobvious difference between the instantly claimed invention and the prior art that would render patentability unto the instantly claimed invention.

Furthermore, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). The limitation of a dosage ranging from between 2 to 3 ounces recited in the instant claims corresponds to a dosage ranging from approximately 59 mL to approximately 89 mL. For a 70 kg patient, this falls well within the range of 0.1 to 2 mL of *Morinda citrifolia* extract per kg of body weight of a patient as taught by Gidlund. Therefore, the applicant has not set forth a persuasive argument that the Gidlund patent teaches a dosage that is unsuitable for selective COX-2 inhibition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER